

Tata Medical Center

14 Major Arterial Road (EW)
Newtown, Rajarhat, Kolkata - 700 160
Tel.: + 91 33 66057000, Email : info@tmckolkata.com
www.tmckolkata.com



Date: 29-May-2026

To,
Head of the Institute,
Tata Medical Center,
14, MAR (EW), New Town, Rajarhat,
Kolkata-700160

Protocol Title: A Phase 3 Randomized Study Comparing JNJ-79635322 versus Teclistamab in Participants with Relapsed or Refractory Multiple Myeloma after 1 to 3 Prior Lines of Therapy, Including an Anti-CD38 Antibody and Lenalidomide (TRIllogy-5)

Protocol Number: 79635322MMY3002

Subject: Ethics committee submission of the above mentioned study documents.

Dear Sir,
Please find enclosed following list of documents of the above mentioned study for EC review & approval.

Sr No	Name of the document	Version	Date
1.	Clinical Protocol	Amendment 1	19-Feb-26
2.	Investigator's Brochure-JNJ-79635322 (ramantamig)	Edition 4	12-Nov-25
3.	Investigator's Brochure-JNJ-64007957 (teclistamab)	Edition 10	9-Oct-25
4.	PI-Dr. Jeevan Kumar-CV	NA	19 Feb 2026
5.	PI-Dr. Jeevan Kumar -GCP	NA	19 Feb 2026
6.	PI-Dr. Jeevan Kumar-MRC	NA	19 Feb 2026
7.	PI-Dr. Jeevan Kumar-Investigator Undertaking	NA	06 Mar 2026
8.	79635322MMY3002_Study Assistance Items	NA	11-Feb-26
9.	79635322MMY3002-Subject Participation Card-India_18 Feb 2026	1	18-Feb-26
10.	79635322MMY3002-Subject Participation Card-India_Hindi FT 27 Feb 2026	1	27 Feb 2026
11.	79635322MMY3002-Subject Participation Card-India_Hindi BT 27 Feb 2026	1	03 Mar 2026
12.	79635322MMY3002-Subject Participation Card-India_Hindi FT and BT COT	NA	4 Mar 2026
13.	79635322MMY3002-Subject Participation Card-India_Bengali FT 18 Feb 2026	1	27 Feb 2026
14.	79635322MMY3002-Subject Participation Card-India_	1	03 Mar

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15.	79635322MMY3002-Subject Participation Card- India_Bengali FT and BT COT	NA	04-Mar-2026
16.	79635322MMY3002-Subject Questionnaire-MySIm-Q- India/English_version of 03Mar2026	NA	3-Mar-26
17.	79635322MMY3002-Subject Questionnaire-EORTC QLQ- C30_English	3.0	NA
18.	79635322MMY3002-Subject Questionnaire-ECRTC QLQ- C30-Telephone Interview Administration Script_English	2.2	NA
19.	79635322MMY3002-Subject Questionnaire-EQ-5D- 5L_India English_v3.0	3.0	NA
20.	79635322MMY3002-Subject Questionnaire-EQ-5D-5L- Version for Interviewer Administration_English_v2.0	2.0	NA
21.	79635322MMY3002-Subject Questionnaire_Patient's Global Impression of Severity (PGIS) of Multiple Myeloma-India/English-Version of 31Jul2023	NA	31-Jul-23
22.	79635322MMY3002-Subject Questionnaire_EORTC IL46_English	NA	NA
23.	79635322MMY3002-Subject Questionnaire_EORTC IL46_Provisional telephone interview administration_English_Version 1.1	1.1	NA
24.	79635322MMY3002-MySIm- Q_translationcertificate_eng-IN_03Mar2026	NA	3-Mar-26
25.	79635322MMY3002-EORTC QLQ-C30_translation certificate_Eng_31Jul2025	NA	31-Jul-25
26.	79635322MMY3002-Voice Script_EORTC QLQ- C30_translation certificate_Eng_13Aug2025	NA	13-Aug-25
27.	79635322MMY3002-EQ-5D-5L_English for India_version 2.0_translation certificate	NA	15-Nov-23
28.	79635322MMY3002-PGIS-MMY - India/English - Version of 31 Jul 2023_translation certificate	NA	31-Jul-23
29.	79635322MMY3002-EORTC IL46_translation certificate	NA	26-Nov-25
30.	79635322MMY3002-Voice script EORTC IL46_translation certificate	NA	26-Nov-25
31.	79635322MMY3002_PRO_AE_Text (India-English) 01Feb2022 Final	NA	1-Feb-22
32.	79635322MMY3002_PRO_AE_Text_Clean Version for Translations_Version 3_27APR2021	NA	1-Feb-22
33.	79635322MMY3002-Subject Questionnaire-MySIm-Q (India-Hindi) 28 Oct 2022	NA	28-Oct-22
34.	79635322MMY3002-Subject Questionnaire-EORTC QLQ- C30_Hindi	3.0	NA
35.	79635322MMY3002-Subject Questionnaire-ECRTC QLQ- C30-Telephone Interview Administration Script_Hindi	2.2	NA
36.	79635322MMY3002-Subject Questionnaire-EQ-5D- 5L_India (Hindi)	2.1	NA

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37.	79635322MMY3002-Subject Questionnaire-EQ-5D-5L- Version for Interviewer Administration_India (Hindi)	1.3	NA
38.	79635322MMY3002-Subject Questionnaire_Patient's Global Impression of Severity (PGIS) of Multiple Myeloma-India/Hindi-Version of 03Aug2023	NA	3-Aug-23
39.	79635322MMY3002-Subject Questionnaire_EORTC IL46_Hindi	NA	NA
40.	79635322MMY3002-Subject Questionnaire_EORTC IL46_Provisional telephone interview administration_Hindi_Version 1.1	1.1	NA
41.	79635322MMY3002-MySIm-Q (0189-TR- 0591)_translationcertificate_IN-hin_28Oct2022	NA	28-Oct-22
42.	79635322MMY3002-EORTC QLQ-C30_translation certificate_Hindi_31Jul2025	NA	31-Jul-25
43.	79635322MMY3002-Voice Script_EORTC QLQ- C30_translation certificate_Hindi_13Aug2025	NA	13-Aug-25
44.	79635322MMY3002-EQ-5D-5L_Hindi for India_version 2.1_translation certificate	NA	15-Nov-23
45.	79635322MMY3002-PGIS-MMY - India/Hindi - Version of 03Aug2023_translation certificate	NA	3-Aug-23
46.	79635322MMY3002-EORTC IL46_translation certificate_Hindi	NA	28-Nov-25
47.	79635322MMY3002-Voice script EORTC IL46_translation certificate_Hindi	NA	28-Nov-25
48.	79635322MMY3002_Patient Reported Outcomes and Adverse Event Reporting Implementation Guide_(India- Hindi) Final	NA	3-Feb-22
49.	79635322MMY3002_PRO_AE_Text_Clean Version for Translations_Version 3_27APR2021_Hindi India	NA	3-Feb-22
50.	79635322MMY3002-MySIm-Q_IN-ben_28OCT2022	Final	28-Oct-22
51.	79635322MMY3002-MySIm-Q (0189-TR- 0591)_translationcertificate_IN-ben_28OCT2022	NA	28-Oct-22
52.	79635322MMY3002- QLQ-C30 Bengali	version 3.0	NA
53.	79635322MMY3002- QLQ-C30 Voice script Bengali	version 2.2	NA
54.	79635322MMY3002-TRANSLATION CERTIFICATE_QLQ- C30	NA	18-Feb-26
55.	79635322MMY3002-Voice Script_TRANSLATION CERTIFICATE_QLQ-C30	NA	06 Feb 2026
56.	79635322MMY3002-Subject Questionnaire-India (Bengali) EQ-5D-5L Digital Self-Complete v2.0	v2.0	NA
57.	79635322MMY3002-Subject Questionnaire-India (Bengali) EQ-5D-5L Digital Interviewer Administration v2.0	V2.0	NA
58.	79635322MMY3002-India (Bengali) EQ-5D-5L Translation Certificate v_2.0	NA	07-Jun-24
59.	79635322MMY3002-Summary_India (Bengali) EQ-5D-5L	NA	07-Jun-24

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Certificate of Translation v_2.0			
60.	79635322MMY3002_Patient's Global Impression of Severity (PGIS) of Multiple Myeloma-India/Bengali-Version of 25 Aug 2023	NA	25 Aug 2023
61.	79635322MMY3002-PGIS-MMY - India/ Bengali - Version of 25 Aug 2023_translation certificate	NA	25 Aug 2023
62.	79635322MMY3002-EORTC IL46_ Bengali	NA	NA
63.	79635322MMY3002-EORTC IL46_Provisional telephone interview administration_Bengali_Version 1.1	version 1.1	NA
64.	79635322MMY3002-EORTC IL46_translation certificate_ Bengali	NA	25-Feb-26
65.	79635322MMY3002-Voice script EORTC IL46_translation certificate_ Bengali	NA	25-Feb-26
66.	79635322MMY3002_Patient Reported Outcomes and Adverse Event Reporting Implementation Guide_(India-Bengali) Final	NA	25 Aug 2023
67.	79635322MMY3002_PRO_AE_Text_Clean Version for Translations_Version 3_27APR2021_ Bengali India	NA	25 Aug 2023
68.	79635322MMY3002-IND--Subject Diary-V1.0_IND-English_14JAN2026	1.0	14-Jan-26
69.	79635322MMY3002-IND--Subject Diary-V1.0_IND-Hindi_14JAN2026	1.0	14-Jan-26
70.	79635322MMY3002-IND--Subject Diary-V1.0_IND-Hindi_Certificate_24 Feb 2026	NA	24 Feb 2026
71.	79635322MMY3002-IND--Subject Diary-V1.0_IND-Bengali_14JAN2026	1.0	14-Jan-26
72.	79635322MMY3002-IND--Subject Diary-V1.0_IND-Bengali_Certificate_25 Mar 2026	NA	25 Mar 2026
73.	Summary of Product Characteristics SmPC (tecavayli)	NA	13 Jun 2024
74.	Master Clinical ICF Version Date:18 Feb 2026, Version Number: 1.0 Site Clinical ICF Version Date:08 Apr 2026, Version Number: 1.1.0 PI: Dr. Jeevan Kumar; Site: Tata Medical Center	1.1.0	08 April 2026
75.	Master Withdrawal Informed Consent Form Version Date: 17 Feb 2026 Version No.:1.0 Site Withdrawal Informed Consent Form Version Date: 08 April 2026 Version No.:1.1.0 PI: Dr. Jeevan Kumar; PI: Tata Medical Center	1.1.0	08 April 2026
76.	Master Pregnancy in Clinical Study ICF Version Date:17 Feb 2026, Version Number:1.0 Site Pregnancy in Clinical Study ICF Version Date:14 Apr 2026, Version Number:2.1.0 PI: Dr. Jeevan Kumar; Site: Tata Medical Center, Kolkata	2.1.0	14 April 2026

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77.	India AV/Audio ICF Version Date: 21 Jul 2025, Version Number: 1.0 Site AV/Audio ICF Version Date: 08 April 2026, Version Number: 1.1.0 PI: Dr. Jeevan Kumar; Site: Tata Medical Center	1.1.0	08 April 2026
78.	Master Clinical ICF Version Date: 18 Feb 2026, Version Number: 1.0 Site Clinical ICF Version Date: 08 Apr 2026, Version Number: 1.1.0 PI: Dr. Jeevan Kumar; Site: Tata Medical Center Translated from English to Hindi on 21 Apr 2026	1.1.0	21 Apr 2026
79.	Master Clinical ICF Version Date: 18 Feb 2026, Version Number: 1.0 Site Clinical ICF Version Date: 08 Apr 2026, Version Number: 1.1.0 PI: Dr. Jeevan Kumar; Site: Tata Medical Center Back Translated from Hindi to English on 21 Apr 2026	1.1.0	21 Apr 2026
80.	Master Withdrawal Informed Consent Form Version Date: 17 Feb 2026 Version No.: 1.0 Site Withdrawal Informed Consent Form Version Date: 08 April 2026 Version No.: 1.1.0 PI: Dr. Jeevan Kumar; PI: Tata Medical Center Translated from English to Hindi on 21 Apr 2026	1.1.0	21 Apr 2026
81.	Master Withdrawal Informed Consent Form Version Date: 17 Feb 2026 Version No.: 1.0 Site Withdrawal Informed Consent Form Version Date: 08 April 2026 Version No.: 1.1.0 PI: Dr. Jeevan Kumar; PI: Tata Medical Center Back Translated from Hindi to English on 21 Apr 2026	1.1.0	21 Apr 2026
82.	India AV/Audio ICF Version Date: 21 Jul 2025, Version Number: 1.0 Site AV/Audio ICF Version Date: 08 April 2026, Version Number: 1.1.0 PI: Dr. Jeevan Kumar; Site: Tata Medical Center Translated from English to Hindi on 21 Apr 2026	1.1.0	21 Apr 2026
83.	India AV/Audio ICF Version Date: 21 Jul 2025, Version Number: 1.0 Site AV/Audio ICF Version Date: 08 April 2026, Version Number: 1.1.0 PI: Dr. Jeevan Kumar; Site: Tata Medical Center Back Translated from Hindi to English on 21 Apr 2026	1.1.0	21 Apr 2026
84.	Master Pregnancy in Clinical Study ICF Version Date: 17 Feb 2026, Version Number: 1.0 Site Pregnancy in Clinical Study ICF Version Date: 14 Apr 2026, Version Number: 2.1.0 PI: Dr. Jeevan Kumar; Site: Tata Medical Center, Kolkata Translated from English to Hindi on 21 Apr 2026	2.1.0	21 Apr 2026
85.	Master Pregnancy in Clinical Study ICF Version Date: 17 Feb 2026, Version Number: 1.0 Site Pregnancy in Clinical Study ICF Version Date: 14 Apr 2026, Version Number: 2.1.0 PI: Dr. Jeevan Kumar; Site: Tata Medical Center, Kolkata Back Translated from Hindi to English on	2.1.0	21 Apr 2026

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86.	FT & BT_Certificate-Dr. Jeevan Kumar-Hin 21 Apr 2026	NA	21-Apr-2026
87.	Master Clinical ICF Version Date:18 Feb 2026, Version Number: 1.0 Site Clinical ICF Version Date:08 Apr 2026, Version Number: 1.1.0 PI: Dr. Jeevan Kumar; Site: Tata Medical Center Translated from English to Bengali on 22 Apr 2026	1.1.0	22 Apr 2026
88.	Master Clinical ICF Version Date:18 Feb 2026, Version Number: 1.0 Site Clinical ICF Version Date:08 Apr 2026, Version Number: 1.1.0 PI: Dr. Jeevan Kumar; Site: Tata Medical Center Back Translated from Bengali to English on 22 Apr 2026	1.1.0	22 Apr 2026
89.	Master Withdrawal Informed Consent Form Version Date: 17 Feb 2026 Version No.:1.0 Site Withdrawal Informed Consent Form Version Date: 08 April 2026 Version No.:1.1.0 PI: Dr. Jeevan Kumar; PI: Tata Medical Center Translated from English to Bengali on 22 Apr 2026	1.1.0	22 Apr 2026
90.	Master Withdrawal Informed Consent Form Version Date: 17 Feb 2026 Version No.:1.0 Site Withdrawal Informed Consent Form Version Date: 08 April 2026 Version No.:1.1.0 PI: Dr. Jeevan Kumar; PI: Tata Medical Center Back Translated from Bengali to English on 22 Apr 2026	1.1.0	22 Apr 2026
91.	Master Pregnancy in Clinical Study ICF Version Date:17 Feb 2026, Version Number:1.0 Site Pregnancy in Clinical Study ICF Version Date:14 Apr 2026, Version Number:2.1.0 PI: Dr. Jeevan Kumar; Site: Tata Medical Center, Kolkata Translated from English to Bengali on 22 Apr 2026	2.1.0	22 Apr 2026
92.	Master Pregnancy in Clinical Study ICF Version Date:17 Feb 2026, Version Number:1.0 Site Pregnancy in Clinical Study ICF Version Date:14 Apr 2026, Version Number:2.1.0 PI: Dr. Jeevan Kumar; Site: Tata Medical Center, Kolkata Back Translated from Bengali to English on 22 Apr 2026	2.1.0	22 Apr 2026
93.	FT & BT_Certificate-Dr. Jeevan Kumar-Ben 22 Apr 2026	NA	22 Apr 2026
94.	79635322MMY3002-EQ-5D-5L_English for India_Summary Certificate of completion	NA	15 Nov 2023
95.	79635322MMY3002-EQ-5D-5L_Hindi for India_Summary Certificate of completion	NA	15 Nov 2023
96.	79635322MMY3002_Form44_CT04_55559_15 Mar 2026	NA	15 Mar 2026
97.	79635322MMY3002-DCGI application	NA	15-Mar-

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98.	79635322MMY3002-IND--Initial Insurance Valid From 01Mar2026 Until 28Feb2027_issued 10Mar2026	NA	10 Mar 2026
99.	CRF 79635322MMY3002 Version 1.02 06MAR2026 - All Forms	1.02	06 Mar 2026
100	79635322MMY3002_ Trilogy 5_ Draft CTA_SST_Dr. Jeevan Kumar 30 Mar 2026	NA	30 Mar 2026
101	India AV/Audio ICF Version Date: 21 Jul 2025, Version Number: 1.0 Site AV/Audio ICF Version Date: 08 April 2026, Version Number: 1.1.0 PI: Dr. Jeevan Kumar; Site: Tata Medical Center Translated from English to Bengali on 24 Apr 2026	1.1.0	24 Apr 2026
102	India AV/Audio ICF Version Date: 21 Jul 2025, Version Number: 1.0 Site AV/Audio ICF Version Date: 08 April 2026, Version Number: 1.1.0 PI: Dr. Jeevan Kumar; Site: Tata Medical Center Back Translated from Bengali to English on 24 Apr 2026	1.1.0	24 Apr 2026
103	FT & BT_Certificate-Dr. Jeevan Kumar-AV ICF-Bengali	NA	24 Apr 2026
104	RSD Approval		
105	IBSC Checklist		
106	SOP 4		

I request you to please review the above-mentioned documents and acknowledge the receipt of the same by signing and dating the below receipt. If you require further information or need any clarifications, please revert to me.

Thanking you

Kind Regards,

Dr. Jeevan Kumar
(Principal Investigator)

HOI acknowledgement:

Dr. P. Arun
Chief Executive Officer
Tata Medical Center
Kolkata